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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,176	04/18/2007	Kiyotaka Nakano	14875-0163US1/C1-A0322P-U	8936
26161	7590	01/25/2010	EXAMINER	
FISH & RICHARDSON PC			DO, PENSEE T	
P.O. BOX 1022			ART UNIT	PAPER NUMBER
MINNEAPOLIS, MN 55440-1022			1641	
NOTIFICATION DATE		DELIVERY MODE		
01/25/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,176	<b>Applicant(s)</b> NAKANO ET AL.
	<b>Examiner</b> Pensee T. Do	<b>Art Unit</b> 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 04 November 2009.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-5 and 12-14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-14 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statements (PTO-1466)  
 Paper No(s)/Mail Date 4/23/07, 6/29/07, 10/3/07, 2/12/08, 6/11/08, 8/29/08  
 0/4/2008, 1/20/00, 2/24/00, 8/6/00 - 10/12/00, 11/4/00, 11/16/00, 12/21/00

4) Interview Summary (PTO-413)

Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Priority***

Application 10582176, PG Pub. No. 20070281327, filed 04/18/2007 is a national stage entry of PCT/JP04/18499, International Filing Date: 12/10/2004 and claims foreign priority to 2003-415733 , filed 12/12/2003.

***Election/Restrictions***

Applicant's election without traverse of group I, claims 1-5, 12-14 in the reply filed on November 4, 2009 is acknowledged.

***Information Disclosure Statement***

IDS papers submitted on April 23, 2007; June 29, 2007; October 3, 2007; February 12, 2008; June 11, 2008; August 29, 2008; September 13, 2008; January 20, 2009; February 24, 2009; August 5, 2009; October 13, 2009; November 4, 2009; November 16, 2009; December 21, 2009 are acknowledged and considered.

***Specification***

The abstract of the disclosure is objected to because it contains more than one paragraph. Correction is required. See MPEP § 608.01(b).

***Claimed Invention***

1. (Original) A method of screening for an agonist antibody, which comprises the steps of:
  - (a) determining the binding activity of a test antibody and selecting an antibody with binding activity;

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- (b) modifying the antibody selected in step (a); and
- (c) determining the agonistic activity of the modified antibody of step (b) and selecting an antibody with agonistic activity.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 40-42, 55, 59 of copending Application No. 10/582,413. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending application '413 claims the a method of screening for an agonist antibody comprising the steps of identifying an antibody that binds to a receptor; modifying the antibody; and determining

the agonist activity of the modified antibody and selecting modified antibody with agonist activity.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 12-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, step (a) recites "a test antibody" and "an antibody" which are unclear if they are the same antibody or not.

Claim 1 recites "the modified antibody" which lacks antecedent basis.

Claim 5 recites "the antibody" which is unclear of which antibody, i.e. the test antibody, the selected antibody, the modified antibody or antibody with agonist activity, in claim 1 it is being referred to.

Claim 12 is unclear if "a test antibody" recited in line 1 and line 3 (step (a) are the same.

Claim 12 also recites "the modified antibody" which lacks antecedent basis.

Claims 1 and 12 are also unclear if "an agonist antibody" in line 1 and "an antibody with agonist activity" in line 5 are the same.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 12-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Fukushima et al. (US PG Pub. No. 2004/0242847 submitted by Applicants in IDS 4/23/2007).

For claims 1 and 12, Fukushima teaches a method of screening for an agonist antibody comprising the steps of: determining the binding activity of an antibody and selecting an antibody with binding activity; (see [231]; modifying the antibody selected; (see example 6) and determining the agonist activity of the modified antibody. (see [0281]-[291]; [324]; [325]).

Regarding claims 2, 3, 13 and 14, Fukushima teaches the modified antibody is sc(Fv)2. (see [230]).

Regarding claim 4, Fukushima teaches the agonist activity is not determined before the antibody is modified. (see example 6; and [324] and [325]).

Regarding claim 5, Fukushima teaches the antibody is against protein expressed on cell membrane. (see [034]).

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Pensee T. Do/  
Examiner, Art Unit 1641

/Mark L. Shibuya/  
Supervisory Patent Examiner, Art Unit 1641